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NOTES

THE OTHER WAR ON DRUGS: FEDERAL PREEMPTION, THE FDA, AND PRESCRIPTION DRUGS AFTER *WYETH V. LEVINE*

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INTRODUCTION

Amidst the debates over health care reform in the United States, there are several common desires that most Americans share: lower costs, greater availability, and continued innovation. Yet as Americans have fixed their attentions on reform legislation, few outside academia have noticed a recent and potent blow to these desires in one of the major sectors of the health care industry. This is, perhaps, because the blow came from the “least dangerous”¹ branch of the federal government. The case was *Wyeth v. Levine*,² and the issue was the doctrine of federal preemption as it applies to the regulation of prescription drug warning labels by the Food and Drug Administration (FDA). Specifically, the Supreme Court ruled in its 2009 decision that the FDA’s judgments regarding prescription drug warning labels do not preempt state tort juries from reaching different, and in this case conflicting, judgments.³ The result is that those who suffer adverse effects from a prescription drug still have standing to sue the drug manufacturer under state tort law for failure to warn, even though the drug’s warning label has met the rigorous standards of, and has been specifically approved by, the FDA.⁴

* J.D., Notre Dame Law School, 2011; B.A., University of Notre Dame, 2008. I would like to thank Hans von Spakovsky and the Center for Legal and Judicial Studies at the Heritage Foundation for the inspiration they gave me to write this Note. I would also like to thank Sheldon Bradshaw, Professor Richard Garnett, and Professor Vincent Rougeau for their helpful comments and advice. *Soli Deo gloria*.

1. THE FEDERALIST NO. 78, at 465 (Alexander Hamilton) (Clinton Rossiter ed., 1961) (description of the federal judiciary).

2. 129 S. Ct. 1187 (2009).

3. See *id.* at 1204.

4. *Id.*

The question of whether federal regulation of prescription drugs should replace conflicting state tort law is a sizable one, for the positions taken by the Court and our nation's policy makers directly impact consumers. While denying preemption provides injured consumers a remedy against manufacturers under state law, it also has significant negative consequences for consumers across the country, touching on the cost, availability, and safety of prescription drugs. If pharmaceutical companies have to bear the burden of complying with both federal law and the common law of all fifty states, even when it is difficult or impossible to do so, the cost of that burden will be passed on to consumers. Also, these companies will be less willing to invest in and produce new products if there is a substantial risk that, even if they comply with the FDA's detailed standards, they may still be sued under a state's common law. Given the increased attention to the problems in our nation's health care system and the widespread desire to make the system more efficient, the consequences of denying the preemptive effect of the already-extensive federal regulation of prescription drugs cannot be ignored. The federal government should be concerned with facilitating the most efficient national market for prescription drugs by providing uniform standards, and yet without federal preemption it only complicates the system by adding a separate set of standards on top of the already-existing common law of the states.

The Roberts Court gave some indication in February 2008 that it would look favorably on federal preemption for FDA regulations.⁵ In *Riegel v. Medtronic, Inc.*⁶ the Court held that the Medical Devices Amendment to the Food, Drug, and Cosmetic Act (FDCA) preempted a plaintiff's state product liability claims alleging defective design of a balloon catheter that the FDA had approved.⁷ The amendment expressly provides that states may not "establish or continue in effect . . . any requirement . . . which is different from, or in addition to, any requirement applicable under [federal law] to the device."⁸ The Court concluded that this prohibition on state regulation logically extends to state common-law rulings as well.⁹ However, about one year after the *Riegel* decision, the Court in *Levine* came down on the opposite side of the preemption debate regarding warning labels on prescription drugs. It gave new life to the "presumption against pre-

5. See, e.g., Editorial, *Medical Double Jeopardy*, WALL ST. J., Mar. 1, 2008, at A8.

6. 552 U.S. 312 (2008).

7. *Id.* at 330.

8. 21 U.S.C. § 360k(a) (2006).

9. *Riegel*, 552 U.S. at 324–25.

emption”¹⁰ which had guided prior Court decisions in conflict of law cases,¹¹ and it suggested that Congress’s desire for preemptive effect must be quite clear in an organic statute,¹² giving little weight to the FDA’s interpretation in favor of preemption.¹³

The Court’s decision in *Levine* is hailed by some as one of the most important victories for consumers in many years. Erwin Chemerinsky claims that the Court’s stand against preemption “preserves the ability of injured consumers to sue pharmaceutical companies for the companies’ failure to provide adequate warnings.”¹⁴ He notes that “[h]ad the Court’s decision gone the other way, it would have barred many lawsuits brought by people who were hurt by prescription drugs.”¹⁵ The decision also satisfies others who view the FDA as largely inadequate at ensuring consumer safety in the pharmaceutical industry.¹⁶ Thomas O. McGarity believes that “[t]he court wisely prevented Wyeth from palming off its responsibility to warn doctors and patients onto an overworked and underfunded federal agency that had been more concerned with meeting industry demands for rapid new drug approvals than with protecting patients from dangerous drugs.”¹⁷ By preserving the right of consumers to bring tort actions in state courts, *Levine* assures that the FDA’s decisions regarding prescription drugs are not conclusive. Many therefore regard the private right of action, in addition to the federal regulations, as a benefit to consumers and necessary in furtherance of their safety.

Others recognize that *Levine* may actually be more detrimental than beneficial to consumers. In his dissent in the case, Justice Alito lamented that the Court’s decision makes state tort juries, rather than the FDA, ultimately responsible for regulating warning labels for prescription drugs.¹⁸ The consequences of this are further explained by Richard Epstein, who notes that

10. *Wyeth v. Levine*, 129 S. Ct. 1187, 1195 n.3 (2009).

11. *Id.* at 1194–95 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

12. *Id.*

13. *Id.* at 1201.

14. Erwin Chemerinsky, *Wyeth Is Victory for Consumers, Blow to Preemption*, TRIAL, May 2009, at 54, 54.

15. *Id.*

16. See, e.g., David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA’s Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 467, 477, 483–95 (2008).

17. Thomas O. McGarity, Op-Ed., *A Victory for Consumers in ‘Pre-emption War,’* HOUS. CHRON. (Mar. 7, 2009, 10:15 CST), <http://www.chron.com/dispatch/story.mpl/editorial/outlook/6298862.html>.

18. *Levine*, 129 S. Ct. at 1217 (Alito, J., dissenting).

opponents of preemption “consider only one kind of error in the drug approval process: its willingness to allow dangerous drugs . . . on the market. But two kinds of errors are evident: letting drugs on the market that should be kept off and taking drugs off of the market that should be left on.”¹⁹ This is indeed the balance that the FDA seeks to strike.²⁰ Just as it is important to protect consumers from the harmful effects of defective medical products, it is equally important to ensure that consumers have access to potentially life-saving prescription drugs. It may in fact be a greater harm to a greater number of consumers if pharmaceutical companies are forced to raise prices, curb innovation, and even remove valuable drugs from the market due to the unpredictable threat of litigation in individual states.²¹

This Note takes the position that the benefits of federal preemption in the pharmaceutical industry far outweigh the costs. Considering the extent to which the FDA regulates prescription drugs, and considering the large national market for them, denying federal preemption actually defeats many of the goals that federalization is meant to accomplish. The need to decrease costs, increase availability, encourage innovation, and create uniform rules in the pharmaceutical industry has become more apparent than ever as a result of the country’s focus on health care, and federal preemption is crucial to satisfying these needs. By eliminating federal preemption in the regulation of prescription drug warning labels, *Levine* will hurt American consumers far more than it will help them.

This argument is still worth making because Congress could effectively overrule *Levine* by enacting an express preemption provision in the FDCA for prescription drugs, similar to that already in force for the type of medical devices that were at issue in *Riegel*. Unfortunately, the political branches of the federal government are currently heading in the opposite direction. Rather than seeking to place medical devices and prescription drugs on the same level by extending federal preemption to the latter, members of Congress have been attempting to undo federal pre-

19. Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. 463, 469 (2009).

20. See Brief for the United States of America as Amicus Curiae Supporting Petitioner at 15–17, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249).

21. See John E. Calfee, *FDA Preemption and Patient Welfare in Wyeth v. Levine* 6 (Am. Enter. Inst. Pub. Pol’y Res., Health Policy Outlook Series No. 9, 2008); James R. Copland & Paul Howard, *In the Wake of Wyeth v. Levine: Making the Case for FDA Preemption and Administrative Compensation* 4 (Manhattan Inst., Project FDA Report No. 1, 2009); Jodie M. Gross & Judi Abbott Curry, *The Federal Preemption Debate in Pharmaceutical Labeling Product Liability Actions*, 43 TORT TRIAL & INS. PRAC. L.J. 35, 36 (2007).

emption for the former. Congressmen Henry Waxman and Frank Pallone recently introduced the Medical Device Safety Act of 2009 which, along with its companion bill introduced by the late Senator Edward Kennedy and Senator Patrick Leahy, would nullify the Court's ruling in *Riegel* by adding language to the Medical Device Amendments of 1976 to ensure that the law does not prohibit suits against device manufacturers.²² An effort to remove federal preemption is sweeping through the executive branch as well. On May 20, 2009, President Obama issued a memorandum to executive departments and agencies prohibiting them from including preemption provisions in codified regulations and regulatory preambles, and requiring them to review, and amend where possible, regulations issued within the past ten years intended to preempt state law.²³ Given current government officials' hostility toward federal preemption, this Note ambitiously aims to persuade them, and the public to whom they are accountable, that federal preemption is crucial in regulating our nation's prescription drug industry, and that its benefits indicate that it should be advanced, not eliminated.

Because cases dealing with federal preemption often raise a plethora of interconnected issues, it is worth noting what this Note does *not* attempt to do. Considerations of the preemptive effect of FDA regulations inevitably involve questions of deference to agency positions. Specifically, much controversy has arisen around the Supreme Court's unwillingness in *Levine* to give deference to the FDA's 2006 preamble. This Note will certainly consider the FDA's position as expressed in the preamble, yet it will not delve into the intricate questions regarding the appropriate degree of judicial deference to such instruments. While these administrative law issues are undoubtedly important in the preemption context, other authors have given them thorough treatment,²⁴ and there is little need to rehash those argu-

22. S. 540, 111th Cong. § 2 (2009); H.R. 1346, 111th Cong. § 2 (2009). For a discussion of the possible consequences of removing preemption for medical devices, see ERNST BERNDT & MARK TRUSHEIM, BERNDT ASSOC., THE ECONOMIC IMPACTS OF ELIMINATING FEDERAL PREEMPTION FOR MEDICAL DEVICES ON PATIENTS, INNOVATION, AND JOBS (2009), <http://www.advamed.org/NR/rdonlyres/DCC3B34A-6257-4A3F-ADE4-4093904178CD/0/EmbargoedBerndtTrusheimPreemptionPaper.pdf>; Hans A. von Spakovsky, *Killing Americans by Stifling Medical Innovation: The Medical Device "Safety" Act of 2009* (The Heritage Found., Legal Memorandum No. 46, 2009), http://thf_media.s3.amazonaws.com/2009/pdf/lm0046.pdf.

23. Memorandum for the Heads of Executive Departments and Agencies, 74 Fed. Reg. 24693 (May 22, 2009).

24. See, e.g., *Preemption of State Common Law Claims*, 123 HARV. L. REV. 262 (2009); Gross & Curry, *supra* note 21; Christina Rodríguez, *The FDA Preamble: A*

ments here. Rather, this Note seeks to analyze the Court's independent judgment and offer a purely normative evaluation of federal preemption in the prescription drug context, analyzing its merits as may be observed by judges and policy makers alike.

This Note will proceed in four main sections. The first presents a brief summary of the facts in *Levine*. The second considers the "presumption against preemption" that guided the Court's decision,²⁵ analyzing it against first principles and in the context of the different forms of preemption. The third section examines the Court's legal reasoning in *Levine*, placing it against the backdrop of the Court's previous preemption decisions. The fourth section considers the policy implications for the pharmaceutical industry, and ultimately for the public, of allowing individual state tort juries to decide matters concerning nationally-marketed prescription drugs. It focuses on, and gives concrete examples of, the effects on consumer safety, availability of prescription drugs, drug prices, and innovation in the pharmaceutical industry.

I. SUMMARY OF *WYETH V. LEVINE*

Levine involved a lawsuit over the injection of the anti-nausea drug promethazine hydrochloride, which Wyeth sold under the brand name Phenergan.²⁶ Phenergan can be administered intravenously through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient's vein.²⁷ The manufacturer's label warned against the danger of gangrene and amputation if the drug entered an artery.²⁸ It allowed the drug to be administered by the "IV-push" method in some circumstances, but it warned that any injection should be through the tubing of an intravenous infusion set that is known to be functioning satisfactorily.²⁹

Backdoor to Federalization of Prescription Warning Labels?, 41 J. MARSHALL L. REV. 161, 169–79 (2007); Catherine M. Sharkey, *What Riegel Portends for FDA Preemption of State Law Products Liability Claims*, 103 NW. U. L. REV. 437 (2008); Katherine M. Glaser, Comment, *A Step Toward Preemption: The Effect of the FDA's 2006 Preamble*, 80 TEMP. L. REV. 871, 893–97 (2007).

25. *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009).

26. *Id.* at 1191.

27. *Id.*

28. *Id.*

29. *Id.* at 1192.

The FDA approved this label in 1998, emphasizing that Wyeth must retain this “identical” verbiage on its final printed label.³⁰

The lawsuit over this label was successful largely because of its tragic facts. Diane Levine, a string bass player and composer of children’s music in Vermont,³¹ went to her health care provider for treatment of a migraine headache and associated nausea.³² She was given an intra-muscular injection of Phenargen, but it did not provide much relief.³³ She returned later in the day and was given an “IV-push” injection of the drug.³⁴ She developed complications from a mistake in the injection, with the drug entering an artery, resulting in gangrene.³⁵ She ultimately had to have her forearm amputated, ending her career as a musician.³⁶

Levine’s situation made for an easy malpractice suit; the physician’s assistant who treated her disregarded Phenargen’s label and pushed the drug into the spot on her arm where inadvertent intra-arterial injection is most likely.³⁷ Accordingly, she won a \$700,000 settlement against the physician’s assistant, the supervising physician, and the clinic.³⁸ But she did not stop there—she proceeded to sue Wyeth in a Vermont state court, arguing that the pharmaceutical firm should have revised its FDA-approved label to bar IV-push injections.³⁹ A jury ruled in her favor, and awarded her \$6,774,000,⁴⁰ which was affirmed by the Vermont Supreme Court.⁴¹

On certiorari before the U.S. Supreme Court, Wyeth argued that it would have been impossible for it to comply with the state-law duty to modify Phenargen’s labeling without violating federal law.⁴² It also argued that recognition of Levine’s state tort action creates an obstacle to the full purposes and objectives of Congress because it substitutes a lay jury’s decision about drug label-

30. *Id.*

31. *Newshour* (PBS television broadcast Nov. 3, 2008), *available at* http://www.pbs.org/newshour/bb/law/july-dec08/scotus_11-03.html.

32. *Levine*, 129 S. Ct. at 1191.

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *Id.* at 1226 (Alito, J., dissenting).

38. Calfee, *supra* note 21, at 1.

39. *Levine*, 129 S. Ct. at 1191–92.

40. *Levine v. Wyeth*, No. 670-12-01 Wncv., 2004 WL 5452938 (Vt. Super. Ct. 2004).

41. *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006).

42. *Levine*, 129 S. Ct. at 1193.

ing for the expert judgment of the FDA.⁴³ The FDA supported this assessment: in the preamble to a January 2006 rule concerning the labeling of drugs, the agency explained its view that “under existing preemption principles, FDA approval of labeling under the [FDCA] . . . preempts conflicting or contrary State law.”⁴⁴ Yet despite the agency’s clear statement in favor of preemption, the Court ruled against Wyeth in a six-to-three decision by Justice Stevens, saying that Congress did not authorize the FDA directly to preempt state lawsuits and that it was not impossible for Wyeth to change its label.⁴⁵ It thus regarded the FDA regulations as merely a floor, rather than a floor *and* a ceiling, arguing that state tort suits will complement FDA regulation and better advance the public health.⁴⁶

II. DEBUNKING THE “PRESUMPTION AGAINST PREEMPTION”

The Supreme Court in *Levine* framed its decision by first laying out the two “cornerstones of preemption jurisprudence”⁴⁷ that would guide its analysis. The first, on its own, is sound: that “the purpose of Congress is the ultimate touchstone in every preemption case.”⁴⁸ The second, however, is problematic, and in a way misconstrues the first: that “[i]n all preemption cases, and particularly in those in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ . . . we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”⁴⁹ This is the “presumption against preemption” that has been mimicked throughout the Court’s preemption jurisprudence for over sixty years with little or no consideration for its proper context or application.⁵⁰ This Note will demonstrate the flaws of this presumption first by returning to first principles, and then by examining its practical application in different preemption contexts.

43. *Id.* at 1193–94.

44. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (to be codified at 21 C.F.R. pt. 201). *See also* Brief for the United States of America, *supra* note 20, at 26–27.

45. *Levine*, 129 S. Ct. at 1204.

46. *Id.* at 1202.

47. *Id.* at 1194.

48. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

49. *Id.* at 1194–95 (quoting *Lohr*, 518 U.S. at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947))).

50. Gross & Curry, *supra* note 21, at 41–42.

A. *First Principles*

The “presumption against preemption” is a curious precedent given the federal Constitution’s clear mandate for the supremacy of federal law. The doctrine of federal preemption is rooted in the Constitution’s Supremacy Clause, which states:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United-States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the contrary notwithstanding.⁵¹

This, of course, is not an unqualified grant of power to the federal government to override state law whenever and on any issue it pleases. Rather, this clause only comes into effect in situations where the federal government exercises a legitimate enumerated power under the Constitution. As Alexander Hamilton explained, the Supremacy Clause does not mean “that acts of the [federal government] which are *not pursuant* to its constitutional powers, but which are invasions of the residuary authorities of the [states], will become the supreme law of the land. These will be merely acts of usurpation, and will deserve to be treated as such.”⁵² Preemption therefore does not expand the scope of the federal government’s powers, for it only applies after the existence of federal power over a subject has already been established.

In determining the preemptive power of federal law, one must always consider the Supremacy Clause in conjunction with the enumerated power Congress is exercising in a given case. Concerns may arise regarding whether a power of the federal government has been overextended to the point where it unduly infringes on powers that are meant to be reserved to the states. However, once it is determined that the federal government is acting in accordance with a constitutionally enumerated power, the preemptive effect of such action cannot be deemed an infringement on the power of the states. Indeed, preemption is often essential to protect individuals and business associations from regulation by two sovereign entities in the same field. According to Justice Harlan, “The constitutional principles of [preemption], in whatever particular field of law they operate,

51. U.S. CONST. art. VI, cl. 2.

52. THE FEDERALIST NO. 33, at 204 (Alexander Hamilton) (Clinton Ros-siter ed., 1961).

are designed with a common end in view: to avoid conflicting regulation of conduct by various official bodies which might have some authority over the subject matter."⁵³

Preemption is often necessary for the purpose of an enumerated federal power to be fulfilled. This is especially true in situations where the states have concurrent sovereignty or an overlapping sovereignty over the subject matter the federal government is seeking to regulate. Some of the Supreme Court's oldest and most famed cases recognized the need for federal preemption in such instances. Most notably, in *McCulloch v. Maryland*,⁵⁴ the State of Maryland was attempting to use its concurrent taxing power to tax a branch of the federal bank established within its jurisdiction.⁵⁵ Having determined the incorporation of the bank was indeed pursuant to an enumerated constitutional power of the federal government, the Court held that the State's power to tax in this instance must be preempted if the legitimate federal objective is to be accomplished.⁵⁶ Chief Justice Marshall explained that, in determining a state law's subordination to federal law:

no principle not declared, can be admissible, which would defeat the legitimate operations of a supreme government. It is of the very essence of supremacy to remove all obstacles to its action within its own sphere, and so to modify every power vested in subordinate governments, as to exempt its own operations from their own influence. This effect need not be stated in terms. It is so involved in the declaration of supremacy, so necessarily implied in it, that the expression of it could not make it more certain. . . . [T]he States have no power, by taxation or otherwise, to retard, impede, burden, or in any manner control, the operations of the constitutional laws enacted by Congress to carry into execution the powers vested in the general government. This is, we think, the unavoidable consequence of that supremacy which the constitution has declared.⁵⁷

53. *Amalgamated Ass'n of St. Employees v. Lockridge*, 403 U.S. 274, 285-86 (1971).

54. 17 U.S. (4 Wheat.) 316 (1819).

55. *Id.* at 317.

56. *Id.* at 424, 436-37.

57. *Id.* at 427, 436.

Often, the enumerated federal power at issue in preemption questions is the power to regulate interstate commerce.⁵⁸ This is true because of its vast expansion over the years, as well as its innate ability to overlap with other powers that would otherwise be reserved to the states. The federal government undoubtedly exercises this power more liberally today than it did in the early days of the Republic; indeed, those who insisted on the inclusion of the Commerce Clause in the Constitution were concerned primarily with the narrow issues of tariffs and trade.⁵⁹ However, the general principle of common interest—that no state should be able to manipulate national commerce policy to the detriment of others—has always been the purpose underlying the Commerce Clause. In discussing the need for federal commerce power, Alexander Hamilton commented, “If the states had distinct interests, were unconnected with each other, their own governments would then be the proper and could be the only depositaries of such a power; but as they are parts of a whole with a common interest in trade, as in other things, there ought to be a common direction in that as in all other matters.”⁶⁰ “Common direction,” therefore, is necessary in commerce to prevent states from pursuing their distinct interests when their common interests in the Union are much greater. This can only be accomplished, moreover, if that “common direction” supplants direction by the states; otherwise, the problem of states pursuing distinct interests still remains, and the “common direction” achieves nothing that could not be achieved by the states individually.

The need for federal supremacy in the area of commerce was at the heart of the Supreme Court’s first great Commerce

58. See U.S. CONST. art. 1, § 8, cl. 3 (“The Congress shall have Power . . . [t]o regulate commerce with foreign Nations, and among the several States, and with the Indian Tribes.”).

59. See, e.g., Alexander Hamilton, *The Continentalist No. V*, in 3 THE PAPERS OF ALEXANDER HAMILTON 75, 75–76 (Harold C. Syrett ed., 1962) (“The vesting Congress with the power of regulating trade ought to have been a principal object of the confederation.”); THE FEDERALIST NO. 42, at 267 (James Madison) (Clinton Rossiter ed., 1961) (“A very material object of this power was the relief of the States which import and export through other States from the improper contributions levied on them by the latter.”); James Madison, *Preface to the Debates in the Convention of 1787*, in 3 THE RECORDS OF THE FEDERAL CONVENTION OF 1787, at 539, 547–48 (Max Farrand ed., 1911) (“Besides the vain attempts to supply their respective treasuries by imposts, which turned their commerce into the neighbouring ports, and to co-erce a relaxation of the British monopoly of the W. Indn. navigation, which was attempted by Virga. the States having ports for foreign commerce, taxed & irritated the adjoining States, trading thro’ them, as N. Y. Pena. Virga. & S—Carolina.”).

60. Hamilton, *supra* note 59, at 78.

Clause case. In *Gibbons v. Ogden*,⁶¹ the Court recognized that, if a state can restrict within its own borders the exercise of a commercial right that Congress has granted, then commerce throughout the whole nation is affected and the granting of such right by Congress is futile.⁶² Specifically, the Court found that a federal coasting statute, enacted under the commerce power and intended to grant licenses to carry on in the coasting trade, must trump a New York state law that restricted the rights of steamboat operators in New York waters.⁶³ Again, Chief Justice Marshall's words on this subject are instructive:

It will at once occur, that, when a Legislature attaches certain privileges and exemptions to the exercise of a right over which its control is absolute, the law must imply a power to exercise the right. The privileges are gone, if the right itself be annihilated. It would be contrary to all reason, and to the course of human affairs, to say that a State is unable to strip a vessel of the particular privileges attendant on the exercise of a right, and yet may annul the right itself; that the State of New-York cannot prevent an enrolled and licensed vessel, proceeding from Elizabethtown, in New-Jersey, to New-York, from enjoying, in her course, and on her entrance into port, all the privileges conferred by the act of Congress; but can shut her up in her own port, and prohibit altogether her entering the waters and ports of another State. To the Court it seems very clear, that the whole act on the subject of the coasting trade, according to those principles which govern the construction of statutes, implies, unequivocally, an authority to licensed vessels to carry on the coasting trade.⁶⁴

The similarities between *Gibbons* and the modern question of FDA preemption for prescription drugs are striking. Both involve the issue of whether an action of the federal government, purportedly exercised in the interest of interstate commerce, must displace interfering state law, even if the state law is pursuant to a power historically reserved to the states. Chief Justice Marshall entertained no presumption that state law should stand merely because it is pursuant to a reserved power of the states rather than to an enumerated power of the federal government. Regarding the effect of the Supremacy Clause, he clearly indicated that

61. 22 U.S. (9 Wheat.) 1 (1824).

62. See *id.* at 211-12.

63. *Id.* at 239-40.

64. *Id.* at 211-12.

[t]he appropriate application of that part of the clause which confers . . . supremacy on laws and treaties, is to such acts of the State Legislatures as do not transcend their powers, but, though enacted in the execution of acknowledged State powers, interfere with, or are contrary to the laws of Congress, made in pursuance of the constitution, or some treaty made under the authority of the United States.⁶⁵

The argument that there should be a “presumption against preemption” in the regulation of prescription drugs because it would supersede a “historic police power of the states,” therefore, holds no weight. Furthermore, both *Gibbons* and the present case involve some sort of “license” granted by the federal government to carry on in a venue of interstate commerce. Congress has entrusted the FDA with the responsibility of regulating prescription drugs, and those manufacturers who comply with all the FDA’s standards with respect to a given drug are thus given the right to market that drug in the interstate commerce system. Where a state may impose further standards, and effectively penalize the manufacturer for exercising its marketing right, the imprimatur of the FDA becomes meaningless.

If the commerce power, or any enumerated power, is to have any significant purpose, then its preemptive effect over contrary or interfering state laws should be coterminous with the extent of the power itself. Without federal preemption, states may try to extract as many gains out of the interstate commerce system as they can. This runs contrary to the principle of common interest that is central to the Commerce Clause. In fact, one may argue that a purported attempt by the federal government to regulate an area of commerce that does not also preclude state regulation over the same area is, in actuality, not pursuant to this power at all. If state laws are not to be preempted in such instance, then the motive of Congress must be some other than the making of uniform commercial standards and regulations. The Commerce Clause was not intended merely to give the federal government the right to pass laws on top of those enacted by the states. It is not an augmentation of the state police power; rather, it is intended to give Congress the ability to standardize and simplify the rights and obligations of

65. *Id.* at 211. Though Chief Justice Marshall speaks directly of the acts of state legislatures, one can assume that the same reasoning extends to interfering state common law rulings as well. The Court addressed, and affirmed, the preemptive effect of federal law over interfering state common law in *Riegel*.

individuals throughout the country in the interest of facilitating interstate commerce.

B. *Forms of Preemption*

In deciding preemption questions, it is necessary to analyze the relationship between federal law and state law. Given the numerous ways in which federal law and state law interact and overlap in our federal system, preemption is applied in several different forms. Sometimes, it is expressly applied by Congress in passing a statute, in which it makes clear its intent to preempt state law in the area it is regulating. This is called express preemption, and to the extent that a statute is considered "clear" and within Congress's enumerated powers, there is rarely any question left for the courts to decide.⁶⁶ When Congress is silent on the matter, as is often the case, state law may still be trumped by federal law by means of implied preemption, of which there are three general types. The first is conflict preemption, which "exists if there is an actual conflict of language . . . [that renders it] impossible for a party to comply with both state and federal requirements."⁶⁷ The second is obstacle preemption. This exists where there is not necessarily a physical impossibility of complying with both federal law and state law, but where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."⁶⁸ Finally, the third type "exists if it appears that the federal statute has occupied the field, blocking state efforts to impose sanctions within that field even if there is no explicit conflict."⁶⁹ Field preemption applies where the federal body of law is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it" or where the domain is "a field in which the federal interest is so dominant that the federal system [is] assumed to preclude enforcement of state laws on the same subject."⁷⁰

Most of the controversy surrounding federal preemption revolves around the forms of implied preemption, for they require courts to decide whether state law should be displaced based on the construction of a federal statute and, as in the present case, of administrative regulations pursuant to it. Even among those who consider themselves Originalists, there are some who reject this form of preemption and its justification

66. See Epstein, *supra* note 19, at 464.

67. Gross & Curry, *supra* note 21, at 44.

68. Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

69. Epstein, *supra* note 19, at 464 (emphasis omitted).

70. Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

under the Supremacy Clause. Most notably, Justice Thomas takes a strong stand against implied preemption, basing his argument largely on the concept of states' rights. He authored a concurring opinion in the *Levine* case, agreeing with the Court's decision based on the Constitution's provisions for dual sovereignty, but disagreeing with the Court's "implicit endorsement of far-reaching implied [preemption] doctrines."⁷¹ Justice Thomas bases his objection to implied preemption on the principles expressed by James Madison in *The Federalist No. 51*, specifically that "the 'compound republic of America' provides 'a double security . . . to the rights of the people' because 'the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivided among distinct and separate departments.'"⁷² He further drew from *The Federalist No. 45* in asserting that "'[t]he powers delegated . . . to the federal government, are few and defined,' and '[t]hose which are to remain in the state governments, are numerous and indefinite.'"⁷³

To suggest that a "presumption against preemption" in implied preemption contexts follows from these federalism principles, however, is misguided. Federalism is not simply synonymous with "states' rights." Rather, it is a system for limiting governmental power by spreading it among separate governments, and it would be contrary to its purpose if one government could simply enact laws on top of those of another. Such would be double jeopardy, not a double security. Furthermore, as Roger Pilon notes, it is equally inappropriate to presume that implied preemption is invalid as it is to presume that express preemption is valid.⁷⁴ In express as well as in implied preemption cases, the underlying statute or regulation may in fact be *ultra vires*, or beyond the powers enumerated to the federal government. Such an overexpansion of federal power indeed seems to be Justice Thomas's main concern.⁷⁵ Yet if it is the case that the federal government's regulation of prescription drugs exceeds its commerce power and simply reaches into the reserved police powers of the states, then the proper response is to disregard the

71. *Wyeth v. Levine*, 129 S. Ct. 1187, 1205 (2009) (Thomas, J., concurring).

72. *Id.* (quoting THE FEDERALIST NO. 51, at 323 (James Madison) (Clinton Rossiter ed., 1961)).

73. *Id.* at 1206 (quoting THE FEDERALIST NO. 45, at 292–93 (James Madison) (Clinton Rossiter ed., 1961)).

74. Roger Pilon, *Into the Pre-emption Thicket: Wyeth v. Levine*, 2009 CATO SUP. CT. REV. 85, 105–06.

75. See *Levine*, 129 S. Ct. at 1205–06 (Thomas, J., concurring).

regulation as unconstitutional. The denial of preemption would be no adequate remedy to such an improper exercise of power. If anything, denying preemption in the prescription drug context suggests even more that the federal government is primarily concerned with exercising control over public health, a power historically reserved to the states. If it were truly concerned with regulating the commercial market for prescription drugs, then preemption would be necessary to achieve its goal of uniformity.

Upon close examination of the three types of implied preemption, it is hard to imagine how the “presumption against preemption” can offer guidance with regard to any of them. Where conflict preemption is at issue, congressional purpose does not matter. The Supreme Court has recognized that “[a] holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility.”⁷⁶ Cases of obstacle preemption do involve a determination of the “object and purpose” of a federal statute, but here it would be counterproductive to assume the continued legitimacy of state law without a thorough examination of the nature of the federal law in question.⁷⁷ The Court’s answer should always strive to allow federal law its fullest effect, and it should not allow this to be tempered by deference to state law. Finally, a “presumption against preemption” in field preemption cases also defies logic. As Gross and Curry explain, “Applying the presumption could result in favoring a state’s limited and potentially insufficient legislative activity in an area in which Congress has taken steps to legislate expansively—a clearly irrational outcome.”⁷⁸ One may safely assume, therefore, that if the federal government has decided to comprehensively regulate a certain field, such regulation should take precedence over less comprehensive regulations by the states.

III. THE COURT’S LEGAL REASONING IN *WYETH V. LEVINE*

Wyeth raised defenses of conflict preemption and obstacle preemption before the Supreme Court in *Levine*,⁷⁹ both of which

76. *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963).

77. See Gross & Curry, *supra* note 21, at 45.

78. See *id.* at 45.

79. See Brief for the Petitioner, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) (No. 06-1249). Richard Epstein takes the position that field preemption is in fact the most appropriate preemption type for FDA drug regulation. See Epstein, *supra* note 19, at 465. Field preemption is one option Congress could consider if it decides to provide an express preemption clause. However, this

the Court rejected. Wyeth first argued that Levine's state-law claims were preempted because it was impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties.⁸⁰ Because the FDA's pre-market approval of a new drug application includes the approval of the exact text in the proposed warning label,⁸¹ Wyeth contended that it could have only changed its label for Phenargen after submitting a supplemental application to the FDA and obtaining the agency's approval.⁸² Wyeth also argued that requiring it to comply with a state-law duty to provide a stronger warning about "IV-push" administration would obstruct the purposes and objectives of federal drug labeling regulation.⁸³ It maintained that Levine's tort claims were preempted because they interfered with "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives."⁸⁴ Accordingly, Wyeth relied on the FDA's position that approval of a new drug under the FDCA and its implementing regulations "establish[es] both a 'floor' and a 'ceiling'" with respect to drug labeling.⁸⁵

In addressing Wyeth's impossibility argument, the Court cited an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval.⁸⁶ This "changes being effected" (CBE) regulation allows manufacturers "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" or "[t]o add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product."⁸⁷ This regulatory exception, however, is only intended to allow a labeling change "to reflect newly acquired information" or "new analyses of previously submitted data."⁸⁸ The Court's decision therefore implied that Wyeth had obtained new information or

Note prefers the conflict and obstacle preemption reasoning espoused by Wyeth and the FDA; it is more narrowly tailored to state laws and rulings that interfere with the federal scheme, and it recognizes that the states still maintain the general power to protect public health.

80. Brief for the Petitioner, *supra* note 79, at 29.

81. 21 C.F.R. § 314.105(b) (2009).

82. Brief for the Petitioner, *supra* note 79, at 31.

83. *Id.* at 40.

84. *Id.* at 46.

85. *Id.* at 45.

86. See *Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009).

87. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C) (2009).

88. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,609 (Aug. 22, 2008) (to be codified at 21 C.F.R. pt. 314.3).

conducted new analyses of existing data, and that it failed to appropriately strengthen its label in response. It is unclear, however, to what “new information” or “new analyses” the Court was referring. As Richard Epstein observes, “The sketchy record reveal[ed] no evidence collected after the drug hit the market indicating a higher incidence of this failure (and perhaps others) that might call for a reevaluation of the risk/reward ratio for [the IV-push] procedure.”⁸⁹ The Court even admitted that “the record [was] limited concerning what newly acquired information Wyeth had or should have had about the risks of IV-push administration of Phenergan.”⁹⁰ While there was evidence of about twenty incidents over the preceding forty-five-year period in which a Phenergan injection resulted in gangrene and an amputation,⁹¹ these incidents did not demonstrate an increased risk that the FDA had not already considered. The approved label warned against these exact side effects. The Court was therefore suggesting that Wyeth should have second-guessed the FDA’s decision in order to fulfill a state-law duty to warn.⁹²

Wyeth’s purposes and objectives argument fared no better, for the Court found that it “relie[d] on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to [preempt] state law.”⁹³ The Court denied Wyeth’s claim that the FDCA established both a floor and a ceiling for drug regulation by asserting that “all evidence of Congress’ purposes is to the contrary.”⁹⁴ To support this assertion, it delved into the history of the FDCA, focusing almost exclusively on Congress’ silence on the issue of preemption for prescription drug regulation. Justice Stevens, writing for the Court, reasoned that “[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express [preemption] provision at some point during the FDCA’s 70-year history.”⁹⁵ The Court also noted that Congress was aware of the operation of state law in this field during this entire period.⁹⁶ Based on these observations, the Court reached the conclusion that Congress must have never intended the FDA’s regulatory judgment to carry any weight in defending against a contrary judgment by a state tort jury.

89. Epstein, *supra* note 19, at 469.

90. *Levine*, 129 S. Ct. at 1197.

91. *Id.*

92. *Id.* at 1203–04.

93. *Id.* at 1199.

94. *Id.*

95. *Id.* at 1200.

96. *Id.*

This conclusion is flawed for several reasons. First, the Court misunderstood what it means to consider Congress's purpose. While it is true that the "purpose of Congress is the touchstone in every preemption case,"⁹⁷ this is not a requirement that Congress expressly mandate preemption in order for it to apply. As Roger Pilon observes, "[T]he Court appears to read [the 'purpose of Congress' principle] as denoting simply Congress's [*preemptive*] purpose, or lack thereof, not its *substantive* purpose in enacting the statute in the first place."⁹⁸ Indeed, if federal preemption were to depend wholly on Congress's specific preemptive purpose, then there would be no implied preemption decisions in the first place. Such an interpretation is especially unsound given the fact that Congress often legislates broadly and cannot possibly foresee every conflict of laws that might arise. The more accurate interpretation of "the purpose of Congress," therefore, is one that aims to discern Congress's substantive intention in passing legislation. This type of assessment was the basis for Wyeth's claim that "[t]he Vermont judgment . . . frustrates . . . Congress's objective of having an expert agency serve as the ultimate regulator of the labeled conditions of use for which a drug is approved."⁹⁹

The Court's conclusion is also flawed because it disregards important historical facts. In assuming "that Congress did not regard state tort litigation as an obstacle to achieving its purposes,"¹⁰⁰ the Court forgot that both "the Food, Drug, and Cosmetic Act (FDCA), which was enacted in 1938, and its primary subsequent amendments, adopted in 1962, predated the . . . expansion of state product liability law" that enabled failure-to-warn lawsuits like Levine's.¹⁰¹ James Copland and Paul Howard of the Manhattan Institute recall that "[i]t was not until 1963, in the landmark California case *Greenman v. Yuba Power Products, Inc.*, that Justice Traynor's doctrine of strict product liability became law,"¹⁰² and it was "not until 1965 that the Second Restatement of Torts launched modern failure-to-warn lawsuits by opining that 'in order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warnings.'"¹⁰³ The fact that Congress was silent as to

97. *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

98. Pilon, *supra* note 74, at 92.

99. Brief for the Petitioner, *supra* note 79, at 40.

100. *Levine*, 129 S. Ct. at 1200.

101. Copland & Howard, *supra* note 21, at 8.

102. *Id.* (referencing 377 P.2d 897 (Cal. 1963)).

103. *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965)).

preemption for prescription drugs thus does not imply that it was aware of state tort suits such as *Levine's* and desired for such suits to persist in the face of detailed and comprehensive FDA regulations.

The Court also disregarded its own precedent in concluding that FDA regulations do not provide both a floor and a ceiling. In *Geier v. American Honda Motor Co.*,¹⁰⁴ the Court was presented with similar preemption issues regarding the Department of Transportation's automotive regulations. There, the Court held that state tort claims premised on Honda's failure to install airbags conflicted with a federal regulation that did not require airbags for all cars.¹⁰⁵ Specifically, the Court found that such claims presented an obstacle to achieving "the variety and mix of devices that the federal regulation sought."¹⁰⁶ In *Levine*, however, the Court tersely dismissed its prior decision, attempting to distinguish it by the fact that the Department of Transportation in *Geier* conducted a formal rulemaking "bearing the force of law."¹⁰⁷ It asserted that the FDA's 2006 preamble stating its preemptive intent does not merit the same deference.¹⁰⁸ Yet as the *Levine* dissent accurately indicated, "the *Geier* Court specifically rejected the argument . . . that conflict preemption is appropriate only where the agency expresses its preemptive intent through notice-and-comment rulemaking."¹⁰⁹ The dissent also noted that "it is irrelevant that the FDA's preamble does not 'bear the force of law' because the FDA's labeling decisions surely do."¹¹⁰ If anything, the FDA's regulations at issue in *Levine* were even more deserving of preemptive effect, for in *Geier* the Department of Transportation had made no statement on the record of preemptive intent whatsoever.

Furthermore, the Court's theory that the FDA's regulations do not provide both a floor and a ceiling is substantively untenable. If these regulations were only to provide minimum requirements for what must be included on a drug's warning label, then it would logically follow that the FDA anticipates fifty different labels for the same drug, one to meet the specific requirements of each state in the Union. This is certainly not the case. The FDA is empowered by Congress to approve the uniform warning label for the entire country that, in its expert judgment, most

104. 529 U.S. 861 (2000).

105. *Id.* at 875.

106. *Id.* at 881.

107. *Wyeth v. Levine*, 129 S. Ct. 1187, 1203 (2009).

108. *Id.*

109. *Id.* at 1227 (Alito, J., dissenting) (citing *Geier*, 529 U.S. at 885).

110. *Id.* at 1228.

appropriately warns against the risks of the drug to which it is attached. As a result of these uniform standards, a separate state law duty would not simply require a manufacturer to alter its label in that state—rather, it would require the manufacturer to change its label in *every* state. The result of the Supreme Court's refusal of preemption, therefore, is that state tort juries can exercise the same authority as the FDA in setting nationwide prescription drug policy.

Finally, the Court mistakenly assumed that state tort suits would aid the FDA in formulating effective label regulations. Yet the *Levine* case itself contradicts this. The Court never suggested what new warnings should have been added through a CBE application to strengthen the label, and to this day, the FDA's substantive requirements for the label remain the same. After reviewing all appropriate information, the FDA announced on September 16, 2009, that it would continue to endorse the warning information previously contained in the Phenergan label, and that it would merely require manufacturers to highlight already-present cautionary information in a boxed warning and to reiterate such information in the label's "Dosage and Administration" section.¹¹¹ The agency's new directive still does not prohibit the "IV-push" method for the drug, despite the fact that the jury in *Levine's* case found that such a prohibition should have been included. Indeed, the "FDA, after thorough review, now has rejected a central premise of *Levine's* argument—i.e., that the IV push method of administration should have been foreclosed entirely."¹¹² While this *ex post facto* review confirms that the Vermont jury's verdict conflicts with the FDA's judgment, the *Levine* decision will nevertheless require courts to reject preemption defenses in failure-to-warn cases unless the FDA has *already* considered and rejected the warning label at issue. Sheldon Bradshaw, former Chief Counsel to the FDA, expects that this will only increase the number of CBE applications submitted to the FDA, thereby stretching the agency's limited resources even further.¹¹³ This extra and unnecessary work will thus inhibit the FDA's ability to formulate effective label regulations, not aid it.

111. Press Release, FDA, FDA Requires Boxed Warning for Promethazine Hydrochloride Injection (Sept. 16, 2009), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182498.htm>.

112. Bert W. Rein, Karyn K. Ablin & Brendan J. Morrissey, Bureau of National Affairs, *FDA's Promethazine Labeling Action: Too Little or Too Late?* 7 PHARM. LAW AND INDUS. REPORT 1151, 2 (2009).

113. Sheldon Bradshaw, New Directions in Federal Preemption: FDA Regulatory Symposium (Sept. 30, 2009), http://www.ehcc.com/presentations/fdasymposium4/bradshaw_1.pdf.

IV. THE PRACTICAL CONSEQUENCES OF DENYING FEDERAL PREEMPTION FOR PRESCRIPTION DRUGS

A. Consumer Safety

Denying federal preemption for prescription drugs will have an adverse effect on consumer safety. Most notably, the presence of state common-law duties on top of FDA regulations will lead to overwarning on prescription drug labels, a problem that the Department of Health and Human Services addressed in its amicus brief in *Levine*.¹¹⁴ It described two distinct ways that overwarning can be detrimental to public health: first, it noted that “[e]xaggeration of risk could discourage appropriate use of a beneficial drug.”¹¹⁵ As drug manufacturers are incentivized to include warnings for every possible risk, they may discourage physicians from prescribing drugs in situations when the drugs may in fact be beneficial. Second, the Department noted that “excessive warnings can cause more meaningful risk information to ‘lose its significance.’”¹¹⁶ As drug labels become cluttered with warnings, most of which relate to trivial risks, physicians may begin to disregard the warnings that are most important. While the FDA can consider these issues in reviewing warning labels, tort juries cannot. Hence the threat of state tort suits may now give the FDA reason to skew its decisions in favor of overwarning.

There are cases that illustrate the potentially harmful effect of pressure on the FDA to increase its warning requirements for certain drugs. One involves a wave of criticism of the FDA alleging inadequate warnings for the selective serotonin reuptake inhibitor (SSRI) class of antidepressants, which was linked to suicidality among young users.¹¹⁷ In response to such criticism, which was spurred by litigation over these drugs, the FDA implemented its strongest “black box” warning for all antidepressants, not just SSRIs.¹¹⁸ However, recent studies have shown that SSRI use actually results in *lower* suicide rates, and that these overly strong warnings have caused a failure to prescribe SSRIs to depressed individuals who genuinely need them.¹¹⁹ As a result,

114. Brief for the United States of America, *supra* note 20, at 17.

115. *Id.* (quoting 71 Fed. Reg. 3935 (2006)).

116. *Id.* (quoting 44 Fed. Reg. 37,447 (1979); accord 71 Fed. Reg. at 3935; 65 Fed. Reg. 81,083 (2000)).

117. Calfee, *supra* note 21, at 3.

118. *Id.*

119. See Jeffrey A. Bridge et al., *Clinical Response and Risk for Reported Suicidal Ideation and Suicide Attempts in Pediatric Antidepressant Treatment: A Meta-analysis of Randomized Controlled Trials*, 297 JAMA 1683 (2007); Jeffrey A. Bridge et al., Research Letter, *Suicide Trends Among Youths Aged 10 to 19 Years in the United States, 1996–2005*, 300 JAMA 1025 (2008); Robert D. Gibbons et al., *Early Evi-*

the risk of suicide for such patients ends up being greater than for those who use these drugs.

Critics of preemption nevertheless claim that the denial of state tort suits would be detrimental to consumer safety, for it would remove the incentive for manufacturers to continue to look for potential risk after obtaining approval by the FDA. As Mary Davis argues,

To permit preemption based on an FDA-approved label, even one that specifically rejected proposed language as unsubstantiated, will create a disincentive to manufacturers to act promptly based on acquired evidence of risk. Indeed, it creates a disincentive to *seek* in the first instance evidence of increased risks or adverse side effects which may be available.¹²⁰

This line of argument, however, ignores the cost of overwarning and “sidestep[s] the tension that often exists between the incentives generated by common-law litigation and the FDA’s own cost-benefit analysis.”¹²¹ It also ignores the fact that federal law already mandates that manufacturers continue to evaluate a drug’s risk and report new information and assessments to the FDA. Federal regulations provide that, after a drug has been approved and marketed, the manufacturer must investigate and report to the FDA any adverse events associated with the use of the drug in humans,¹²² and must periodically submit any new information that may affect the FDA’s previous conclusions about the safety, effectiveness, or labeling of the drug.¹²³ While it is important that manufacturers continue to improve the safety of their products, federal law, not state law, should be the standard.

dence on the Effects of Regulators’ Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents, 164 AM. J. PSYCHIATRY 1356 (2007); Jens Ludwig, Dave E. Marcotte & Karen Norbert, *Anti-depressants and Suicide*, 28 J. HEALTH ECON. 659 (2009); Robert E. McKeown, Steven P. Cuffe & Richard M. Schulz, *U.S. Suicide Rates by Age Group, 1970–2002: An Examination of Recent Trends*, 96 AM. J. PUB. HEALTH 1744 (2006); Cynthia R. Pfeffer, Editorial, *The FDA Pediatric Advisories and Changes in Diagnosis and Treatment of Pediatric Depression*, 164 AM. J. PSYCHIATRY 843 (2007); Gregory E. Simon et al., *Suicide Risk During Antidepressant Treatment*, 163 AM. J. PSYCHIATRY 41 (2006); Madhukar H. Trivedi et al., *Evaluation of Outcomes with Citalopram for Depression Using Measurement-Based Care in STAR*D Implications for Clinical Practice*, 163 AM. J. PSYCHIATRY 28 (2006).

120. Mary J. Davis, *The Battle over Implied Preemption: Products Liability and the FDA*, 48 B.C. L. REV. 1089, 1151 (2007).

121. Copland & Howard, *supra* note 21, at 11.

122. 21 C.F.R. § 314.80 (2009).

123. *Id.* § 314.81.

B. Availability of Prescription Drugs

Levine will also likely inhibit consumers' access to beneficial prescription drugs. As manufacturers face potentially exorbitant litigation costs, many will opt to remove certain drugs from the market even though they have been approved by the FDA. The most famous example of this is the morning-sickness drug Bendectin, which became the subject of junk-science allegations that it caused birth defects. It "was used by as many as [twenty-five] percent of all expectant mothers in 1980," but by 1983, its manufacturer pulled it from the U.S. market in the face of \$18 million in annual legal bills which were barely offset by \$20 million in annual sales.¹²⁴ Over thirty studies have failed to find a link between Bendectin and birth defects, and yet the drug remains unavailable to women in the U.S. even while it is still marketed in other parts of the world.¹²⁵ Furthermore, since it was discontinued in the U.S., "the percentage of pregnant women hospitalized each year for morning sickness has doubled, but the incidence of birth defects has not declined."¹²⁶ Such statistics are indeed taken into account by the FDA during the drug approval process. However, if the FDA's judgments do not have preemptive effect, the agency's cost-benefit analysis becomes meaningless, as state tort juries can effectively force drugs that are largely beneficial to society off the market.

C. Drug Prices

Preserving tort liability for FDA-approved prescription drugs will increase the cost of drugs as well. Pharmaceutical companies must plan ahead for future litigation expenses they can reasonably expect to incur, and this ultimately is reflected in the price consumers pay for drug products. Because manufacturers cannot be sure that their compliance with FDA standards will shield them from state tort litigation, they must expect greater litigation expenses, and thus must charge more for their products. Health economist Richard Manning, who conducted a pair of studies that examined the effects of the tort liability system on the price

124. Copland & Howard, *supra* note 21, at 10. See also Marvin E. Jaffe, *Regulation, Litigation, and Innovation in the Pharmaceutical Industry: An Equation for Safety*, in *PRODUCT LIABILITY AND INNOVATION: MANAGING RISK IN AN UNCERTAIN ENVIRONMENT* 120, 126 (Janet R. Hunziker & Trevor O. Jones eds., 1994) (using Bendectin as an example of the "disparities between the goals of the regulatory process and the tort liability system").

125. Copland & Howard, *supra* note 21, at 10.

126. *Id.*

of vaccines in the 1980s, has demonstrated this effect.¹²⁷ Whereas most vaccines doubled or tripled in wholesale price between 1980 and 1989,¹²⁸ two vaccines that were particularly litigation-prone exhibited a much more dramatic increase in price. The price of the oral polio vaccine increased almost sevenfold, and the price of the DPT vaccine increased by a factor of more than forty.¹²⁹ Furthermore, the price effects of extensive litigation were exacerbated by the fact that many manufacturers of these vaccines ended up taking them off the market, decreasing the supply of vaccines and creating persistent vaccine shortages.¹³⁰

D. Innovation

Finally, denying federal preemption in prescription drug regulation will deter innovation in the pharmaceutical industry. As Justice O'Connor has recognized, the threat of enormous awards in state tort suits "has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market."¹³¹ Because excessive tort liability increases the expected costs of researching and developing new drugs, many manufacturers simply find it unprofitable to engage in such innovation. This is especially true for drugs intended for healthy patients, such as children and pregnant women, for in such cases it is much easier to blame any future ailment, regardless of actual cause, on the use of the drug.¹³² One president of a major pharmaceutical company posed the question: "Who in his right mind . . . would work on a product today that would be used by pregnant women?"¹³³ Vaccines have also proven particularly susceptible to litigation, and hence investment in them has been impeded given their high risk and relatively low profit margin. The Institute of Medicine has recognized that liability risks "act

127. See Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J.L. & ECON. 247, 273 (1994) [hereinafter Manning, *Changing Rules*]; Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & ECON. 203, 234 (1997).

128. Manning, *Changing Rules*, *supra* note 127, at 254, 257.

129. *Id.* at 257.

130. Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 HEALTH AFF. 622 (2005).

131. *Browning-Ferris Indus. of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part).

132. See PETER W. HUBER, *LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES* 155 (1988).

133. *Id.*

as a deterrent to vaccine production and thereby threaten the public's health."¹³⁴ Progress on many potentially valuable vaccines, such as one for the AIDS virus,¹³⁵ is being impeded by the threat of liability, for tort juries merely focus on the alleged harm in a given case without considering a product's broader societal value.

CONCLUSION

Wyeth v. Levine was a setback for American consumers and for the federal system that is intended to protect them. The American federal system is not one in which one state's judges, trial juries, and trial lawyers should be shaping policy in the national marketplace. Yet this is precisely what the Vermont courts have done. Though the intention of concurrent state liability for prescription drugs is to protect consumers, it does not accomplish this goal—it undermines it. In allowing both the federal government and state governments to regulate prescription drugs, the Supreme Court disregards the fact that unified national standards better promote consumer safety, lower the cost of beneficial drugs, provide more consumer choice, and encourage innovation. The Court also assumes that state tort juries can make the same kind of cost-benefit analysis as the FDA. They cannot. The very purpose of the FDA is to ensure that standards are set by experts who take into account the full range of scenarios for society, not just the unfortunate facts of one specific case. The benefit of a particular drug to the public as a whole may outweigh the potential risk to a select number of people, and physicians must be the ones to take those risks into account. If Congress is truly serious about improving efficiency and effectiveness in the health care industry, then it must address this problem the Court has created. The answer is not to further diminish the preemptive effect of FDA regulations in other areas, but to restore the preemption of state failure-to-warn suits for prescription drugs.

134. INST. OF MED., VACCINE SUPPLY AND INNOVATION 2 (1985).

135. See Jon Cohen, *Is Liability Slowing AIDS Vaccines?*, 256 SCI. 168 (1992).